

Dear Mr. Reilly:

During the past several months, we have been attempting to contribute, in as positive and substantive a manner as possible, to the Environmental Protection Agency's draft risk assessment and policy guide on environmental tobacco smoke (ETS). Our primary purpose in writing this letter is to raise with you certain concerns that have not been adequately addressed by the Agency thus far. We also want to take this opportunity to comment on a number of reports that have appeared recently in the press concerning the composition of the Science Advisory Board (SAB) panel that has been convened to consider the Agency's draft ETS documents.

As you know, the SAB panel selected to review the Agency's risk assessment and policy guide on ETS is scheduled to meet today and tomorrow. Our understanding is that, after having received the SAB's comments, Agency personnel will evaluate the drafts in light of all comments received, including all public comments that have been submitted. We also note that many important public comments -- including comments from a number of eminent researchers -- have not been provided to the SAB for its deliberations and therefore must be taken into account by Agency staff during the post-SAB stage of the review process.

For the reasons briefly summarized below, we cannot overemphasize the importance of careful and objective review of the draft ETS documents by the SAB as well as by senior officials at the Agency. On a number of occasions, we have conveyed to staff our serious concerns about the process that has been used in preparing the drafts currently being reviewed. Those concerns help to explain the unique importance of SAB and senior level Agency review to the integrity of the draft documents on ETS. The concerns that we have raised concerning the process that led to the current draft documents include the following:

-- The draft ETS policy guide has been characterized by Agency staff as a summary of the draft risk assessment and the ETS technical compendium on which Agency staff and consultants have been working. The technical compendium has not yet been reviewed by an SAB panel and, on the current schedule, is unlikely to be available to senior Agency officials while the risk assessment and policy guide are under active review.

-- On many occasions, the Agency has emphasized the importance of not permitting risk management decisions to be intertwined with or to precede risk assessment decisions. In this case, however, the Agency staff somehow felt it appropriate to prepare, and to seek immediate review of, an ETS policy guide before an ETS risk assessment had been reviewed and

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released in final form. As noted, the policy guide also has preceded completion of the technical compendium on ETS, one of the documents the policy guide purports to summarize.

-- The Agency already has released a "fact sheet" on ETS, which covers many of the same issues as the three documents just described but has never been submitted to an SAB for review. This suggests Agency prejudgment on ETS. It also calls into question the commitment of Agency staff to consider in an appropriately serious and objective fashion the voluminous comments that have been submitted on the documents currently under review.

We had hoped and expected that the negative effects of the problems described above would be ameliorated by the SAB review process. Unfortunately, events of the past few weeks have suggested the contrary. While we intend to make presentations to the SAB, according to the ground rules that have been set by SAB staff, a number of circumstances have developed that, at the very least, raise questions about the integrity of the review process.

Our initial understanding was that only scientists with expertise in the relevant disciplines who had not taken a firm position on ETS and had not played an active political role with respect to smoking issues would be included on the SAB panel reviewing the ETS risk assessment and policy guide. Based on that understanding, and at the request of the SAB staff, we and others proposed candidates for inclusion on the panel.

None of these candidates was selected and, to the best of our knowledge, none was even contacted to participate in the SAB review. All of the scientists whose names we submitted have strong and pertinent academic credentials, and none was affiliated with any private interest group having a stake in the outcome of the SAB review process. In contrast, we understand that three of six persons suggested by anti-smoking activists were selected to serve on the panel. None of these individuals met the criteria that we understood would guide the SAB selection process.

We also have learned that several other SAB panel members actively participated in the preparation of the documents being reviewed by the SAB. Whether those panelists will be able to ignore that interest as they participate in the SAB's deliberations remains, of course, to be seen. However, the selection of such people by the the Agency to serve on the SAB panel does not appear to meet the statutory admonition that the SAB be "fairly balanced" and "independent."

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These facts make ironic, and most disturbing, recent press reports charging that the current SAB panel is "slanted" in favor of the tobacco industry. The facts do not support such a claim. Nevertheless, the widespread dissemination of the claim in the press has inappropriately politicized the review process and raises questions about the SAB's ability to perform its statutory responsibilities.

So far as the charge of industry favoritism is concerned, several related points need be made. As the press has reported, one SAB panel member serves on the Science Advisory Board of the Center for Indoor Air Research (CIAR), which receives funding from tobacco companies and others. Several other panel members have reviewed one or more research proposals submitted to CIAR, have commented on the CIAR research agenda or -- in one case -- has received a CIAR research grant. Another panel member discussed with one of The Institute's member companies -- well before his selection as a panel member -- the possibility of obtaining company support for a specific research project to be undertaken at his university in accordance with the university's standard practices for contract research. In fact, no such support has been offered, despite press reports to the contrary.

Significantly, none of the scientists mentioned in recent press reports has ever demonstrated bias in favor of the industry with respect to ETS or any other issue. And no instance of such bias has even been alluded to in any of the press reports that have appeared. Indeed, certain of the scientists who have been listed as having ties to the industry or to industry-sponsored organizations have published articles inconsistent with the industry's position on ETS. In contrast, the record of another member of the SAB panel -- Dr. David Burns, who was nominated for the panel by an anti-smoking organization -- is quite different, as the SAB staff itself has recognized.

Moreover, as you may be aware, none of the scientists mentioned in the recent press reports as having tobacco industry ties was proposed by the industry to participate in the SAB review process. Four of the six scientists who have been mentioned are standing members of the Agency's SAB committee on indoor air quality and, as a result, automatically became members of the current panel. The other two were either nominated by private non-industry sources or by the Agency staff.

The controversy surrounding the current SAB panel would not have arisen, of course, if the criteria that we originally understood would guide the SAB selection process had been utilized. In view of the developments we have described, we believe that certain additional safeguards should

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be considered by the Agency to preserve the integrity of the ongoing review.

Specifically, we urge that the following steps be taken by the Agency after the current SAB panel's comments on the draft ETS risk assessment and policy guide have been received:

(1) Final Agency consideration of the ETS risk assessment and policy guide should not be undertaken until the ETS technical compendium has been completed and has been reviewed by an appropriately constituted SAB panel.

(2) The panel convened to review the technical compendium should be composed of scientists (a) having unquestionable expertise in relevant disciplines, (b) who have not commented on or otherwise participated in the drafting of the technical compendium or other Agency documents concerning ETS, (c) have not been active participants in the ongoing political controversies relating to tobacco and (d) have not consulted with or been a member of any entity having an interest in the conclusions reached in the technical compendium. We also suggest, as a means of ensuring that the panel is both above reproach and perceived to be so, that recommendations for membership not be solicited or accepted from any entity having an interest or stake in the panel's deliberations, including Agency staff responsible for preparation of the technical compendium, risk assessment or policy guide.

(3) After the technical compendium has been completed, the ETS risk assessment and policy guide should be reviewed by either the SAB panel given responsibility for reviewing the technical compendium or by an entirely new panel selected in accordance with the criteria described in point (2) above.

(4) Finally, and even if none of the steps described in points (1) through (3) above is taken, we urge that none of the Agency's ETS documents be released until after they have undergone careful senior level Agency review.

We thank you in advance for considering the requests we have made and stand ready to answer any questions you or others within the Agency may have concerning the matters covered in this letter.

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